

c.) Remarks

As of this response, claims 7-15 remain pending.

Outstanding Rejections/Objections

The Examiner has entered the following rejections:

1. Claims 7 and 9-13 are rejected under the judicially created doctrine of obviousness-type double patenting.
2. Claims 11-15 are rejected under 35 USC § 112, second paragraph.
3. Claims 7-15 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent 6,290,726 to Pope et. al. (“Pope ‘726”) in view of U.S. Patent 4,281,420 to Raab (“Raab ‘420”) and U.S. Patent 5,674,293 to Armini et. al. (“Armini ‘293”).

Applicants address each rejection in turn.

1. Rejection of Claims 7 and 9-13 for Obviousness-Type Double Patenting

The examiner has rejected claims 7 and 9-13 are rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent 6,652,586 (“the ‘586 patent). Although the applicants believe that the pending claims are patentably distinct over the disclosures of the ‘586 patent, applicants submit herein a terminal disclaimer in order to more readily place the application in condition for allowance. Accordingly, applicants assert that the rejection for obviousness-type double patenting over the ‘586 patent has been overcome and respectfully request withdrawal of the rejection.

2. Rejection of Claims 11-15 under 35 USC § 112, second paragraph

The examiner has rejected claims 11-15 are rejected under 35 USC § 112, second paragraph. The examiner notes that in claim 11, line 3, the expression “the prosthesis body” lacks antecedent basis.

Applicants herein amend the claims to address the issue. Applicants thank the examiner for bringing this issue to their attention. As the problem has been corrected by the amendments herein, applicants respectfully request withdrawal of this rejection.

3. Rejection of Claims 7-15 under 35 USC § 103(a)

The examiner has rejected claims 7-15 under 35 USC § 103(a) as being unpatentable over Pope '726 in view of Raab '420 and Armini '293. Applicants respectfully traverse the rejection.

As applicants have argued in their previous responses, none of the three cited references teaches or suggests a vertebral disc prosthesis having a diffusion bonded blue-black or black oxidized zirconium surface articulating against cross-linked polyethylene (XLPE). Importantly, none of the cited references teaches or suggests the diffusion bonded blue-black or black oxidized zirconium surface articulating against XLPE in any context, so it difficult to understand how the combination of the three references would teach or suggest the combination to one of ordinary skill in then art at the time the invention was made. The examiner cites *Kalman v. Kimberly Clark*, 218 USPQ 781 (CCPA 1983) for the proposition that the law of anticipation does not require that a reference “teach” what the subject patent teaches, but rather that the claims under attack “read on” something in the reference. Applicants are a bit unclear why the examiner even cites this authority, as it relates to rejections under § 102, while the outstanding rejection is under § 103.

With regard to the law of obviousness, the examiner (citing various authorities) states that “one cannot show nonobviousness by attacking the references individually. However, to make a *prima facie* case of obviousness, it is required that the reference teachings “appear to have suggested the claimed subject matter.” *In re Rinehart*, 537 F.2d 1048 (CCPA 1976). To establish *prima facie* obviousness of a claimed invention, all of the limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). In order to determine whether the combined references, in context, teach the claimed subject matter, it is necessary to analyze each reference for what it teaches individually. For this reason, the examiner’s characterization of the applicants arguments as “attacking the references individually” is inaccurate. The applicants are analyzing each reference to show that the combination fails to teach or suggest all limitations of the rejected claims and that therefore, the examiner has failed to make a *prima facie* case of obviousness. While applicants have discussed each reference individually, they have also noted that the combination fails to teach the claimed invention. If a teaching or suggestion of one or more limitations of the claimed invention is absent from each of the references of the combination, it is difficult to understand how the combination of the references would somehow teach or suggest (the missing limitation of) the claimed invention.

With respect to the outstanding rejection, applicants assert that none of the cited references teaches or suggests a vertebral disc prosthesis having a surface of diffusion-bonded blue-black or black oxidized zirconium articulating (i.e., being in weight-bearing contact) against cross-linked polyethylene. Because none of the references teach or suggest this individually, the combination of the three also fails to teach or suggest this. At page 5 of the outstanding office action, the examiner states that:

Regarding the diffusion-bonding process, it is noted that black oxidized zirconium utilized by Armini et al. appears to be substantially identical to the black oxidized zirconium claimed, although produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing a unobvious difference between the two (citation omitted).

The examiner concedes that the surface of Armini '293 is produced by a different process than the oxidized zirconium surfaces of the rejected claims. Applicants assert that the different processes result in different surfaces. To this end, applicants herein submit the evidence suggested by the examiner. This evidence is provided in an accompanying Rule 132 declaration. The declaration is provided by Vivek Pawar, an engineer at Smith & Nephew, Inc. with considerable experience in this field. Attached to, and forming a part of, the Pawar declaration, is data comprising SEM and Auger electron data of the oxidized zirconium of the instant claims. The Auger data provided is particularly instructive because Armini '293 also provides Auger data, thereby allowing for a direct comparison using the same frame of reference.

Applicants first refer to FIG. 5 of Armini '293 which shows an Auger electron spectrum of the oxide of Armini '293. At early sputtering times (i.e., less than approx. 12 minutes), the Armini '293 composition consists of zirconium, carbon, oxygen, platinum and cobalt, which significant amounts of carbon and platinum. The presence of platinum dominates the Armini '293 composition at intermediate sputtering times, while cobalt and chromium are dominant at long sputtering times. In the accompanying Rule 132 declaration, applicants submit an Auger electron spectrum of the oxidized zirconium of the instant claims. In stark contrast to the surface of Armini '293, the oxidized zirconium of the instant claims substantially consists of only zirconium and oxygen. These two elements sum to close to 100% (impurities may comprise a minor component) at the surface and at all depths as the bulk substrate is approached. From this data, it is clear that the two surfaces are not "substantially identical" as the examiner asserts, and

in fact are quite different compositionally. In his Rule 132 declaration, Mr. Pawar discusses the data and the significance of the data as it relates to the differences between the surface of Armini '293 and the oxidized zirconium of the pending application.

Further to this end, applicants also provide a technical article of Hobbs et al. (*Int. J. Appl. Ceram. Technol.*, 2 [3] 221-246 (2005)). This article is provided in an Information Disclosure Statement filed with this response. This article characterizes the in-situ formed, diffusion-bonded oxide of the instant claims formed on a Zr alloy having between 2% and 3% niobium (Nb). Figures 7 and 9 (on pages 228 and 231, respectively) of the Hobbs articles demonstrates that the oxide consists substantially of only Zr, Nb, and O. The only other component identified was silicon at impurity levels (<100 ppm). This is discussed at page 238. The article also demonstrates that the oxide formed in high temperature oxidation is one having a specific structure (see pages 223 and 232-242). The reference of Hobbs demonstrates that the diffusion-bonded oxides of the present invention differ compositionally from those of Armini '293 and that diffusion-bonded oxides formed by high temperature oxidation have unique structural characteristics as well.

In summary, applicants respectfully assert that the examiner has failed to make a prima facie case of obviousness because none of the cited reference teach or suggest a vertebral disc prosthesis having the specific diffusion bonded blue-black or black oxidized zirconium surface articulating against cross-linked polyethylene. None of the references teach the diffusion bonded blue-black or black oxidized zirconium surface of the instant claims. To this end, applicants have provided data and a literature reference to rebut the assertion of the examiner that the black oxidized zirconium utilized by Armini '293 is substantially identical to the black oxidized zirconium claimed. For these reasons, applicants respectfully assert that the rejection under 35

USC § 103(a) over Pope '726 in view of Raab '420 and Armini '293 has been overcome. In view of these arguments and evidence, applicants respectfully request withdrawal of the outstanding rejection.

d.) Conclusions

In light of the terminal disclaimer, amendments and arguments made herein, Applicants respectfully assert that the pending claims are in condition for allowance. Because the Examiner's rejections have been addressed, Applicants respectfully request withdrawal of the outstanding rejections. Accordingly, Applicants earnestly request allowance of the application. This is intended to be a complete response. If any issues remain outstanding, please contact the undersigned for resolution of the same.

Applicants hereby authorize the Commissioner to draw the fee for filing the Information Disclosure Statement (\$180.00) and the fee for filing the Terminal Disclaimer (\$130.00) and any additional fees associated with this filing from Deposit Account No. 06-2375, under Order No. P02228US1/10105654, from which the undersigned is authorized to draw.

Respectfully submitted,

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